

**APPENDIX D:
Nonstatistical Informed Consent Forms and Scripts**

Informed Consent Form: Referral Agent Focus Group

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting focus groups to learn about the perceptions and experiences of referral agents with durable medical equipment and the competitive bidding program in the area. These focus groups will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a focus group because you are a referral agent for Medicare beneficiaries and their durable medical equipment. A total of 6 focus groups with both suppliers and referral agents are being held as part of the study and each focus group will have up to 10 participants and two moderators. Abt Associates will conduct the focus groups and other forms of data collection, analysis, and reporting. Andrea Hassol is the Principal Investigator at Abt Associates.

You are being asked to sign a consent form to participate in the focus group.

PROCEDURES

You will be asked to join with other referral agents in a 1.5-hour discussion about the Medicare competitive bidding program for DMEPOS. A researcher will facilitate the group in discussing your experiences with the Medicare competitive bidding program. The focus group will not be audio or video taped.

The discussion will be confidential. You can refuse to take part in this focus group if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer a question during the focus group, without affecting your continued participation in the group or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researchers do not foresee any possible risks to you from participating in this focus group, other than the minimal risk that your confidentiality might not be preserved. One of the risks to confidentiality is that other focus group participants may repeat what they hear during the group. The researchers will do everything allowable by law to assure that your privacy is protected and will ask all participants at the beginning of the focus group not to repeat the focus group discussion outside of the group.

Additionally, the focus group discussion notes will be labeled with a study code, not your or another participant's name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments, and those of others in the focus group, will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the focus group.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from joining the focus group, although you may benefit from the opportunity to hear about others’ experiences with the competitive bidding program.

COMPENSATION

You will receive \$75 for participating in the focus group today, after the discussion is held. You will also receive dinner at the focus group facility.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to participate in the focus group. If you decide not to participate in the focus group, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Andrea Hassol of Abt Associates (617 349-2488) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Hassol at:

Andrea Hassol
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

You may also phone Teresa Doksum, the chairperson of Abt Associates’ Institutional Review Board (617 349-2896) if you have other questions about your rights as a focus group participant. All of these numbers are toll calls.

STATEMENT BY FOCUS GROUP MODERATOR IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

Moderator’s Name

Moderator’s Signature

Date

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

Volunteer's Name

Volunteer's Signature

Date

Informed Consent Form: Supplier Focus Group

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting focus groups to learn about the perceptions and experiences of referral agents with durable medical equipment and the competitive bidding program in the area. These focus groups will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a focus group because you are a DMEPOS supplier who provides these supplies to Medicare beneficiaries

A total of 6 focus groups with both suppliers and referral agents are being held as part of the study and each focus group will have up to 10 participants and two moderators. Abt Associates will conduct the focus groups and other forms of data collection, analysis, and reporting. Andrea Hassol is the Principal Investigator at Abt Associates.

You are being asked to sign a consent form to participate in the focus group.

PROCEDURES

You will be asked to join with other suppliers in a 1.5-hour discussion about the Medicare competitive bidding program for DMEPOS. A researcher will facilitate the group in discussing your experiences with the competitive bidding program. The focus group will not be audio or video taped.

The discussion will be confidential. You can refuse to take part in this focus group if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer a question during the focus group, without affecting your continued participation in the group or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researchers do not foresee any possible risks to you from participating in this focus group, other than the minimal risk that your confidentiality might not be preserved. One of the risks to confidentiality is that other focus group participants may repeat what they hear during the group. The researchers will do everything allowable by law to assure that your privacy is protected and will ask all participants at the beginning of the focus group not to repeat the focus group discussion outside of the group.

Additionally, the focus group discussion notes will be labeled with a study code, not your or another participant's name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments, and those of others in the focus group, will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the focus group.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from joining the focus group, although you may benefit from the opportunity to hear about others’ experiences with the competitive bidding program.

COMPENSATION

You will receive \$75 for participating in the focus group today, after the discussion is held. You will also receive dinner at the focus group facility.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to participate in the focus group. If you decide not to participate in the focus group, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Andrea Hassol of Abt Associates (617 349-2488) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Hassol at:

Andrea Hassol
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

You may also phone Teresa Doksum, the chairperson of Abt Associates’ Institutional Review Board (617 349-2896) if you have other questions about your rights as a focus group participant. All of these numbers are toll calls.

STATEMENT BY FOCUS GROUP MODERATOR IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

Moderator’s Name

Moderator’s Signature

Date

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

Volunteer's Name

Volunteer's Signature

Date

Informed Consent Form: Key Informant Discussion—Beneficiary Group/Advocate

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of beneficiary groups and advocates. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a discussion because you are with a beneficiary group or are an advocate for Medicare beneficiaries and their durable medical equipment.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the discussions and other forms of data collection, analysis, and reporting. Andrea Hassol is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the durable medical equipment and the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

The discussion notes will be labeled with a study code, not your name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the interview.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the discussion, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Andrea Hassol of Abt Associates (617 349-2488) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Hassol at:

Andrea Hassol
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STATEMENT BY INTERVIEWER IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

Interviewer’s Name Interviewer’s Signature Date

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

Volunteer’s Name Volunteer’s Signature Date

Informed Consent Form: Key Informant Discussion—CMS Officials/ Bidding Program Managers

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of CMS officials and bidding program managers. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a discussion because you are a CMS official/bidding program manager who works with Medicare beneficiaries to receive durable medical equipment.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the focus groups and other forms of data collection, analysis, and reporting. Andrea Hassol is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part in this discussion if you wish without losing any rights or benefits related to my professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

The discussion notes will be labeled with a study code, not your name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the discussion.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the interview, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Andrea Hassol of Abt Associates (617 349-2488) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Hassol at:

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STATEMENT BY INTERVIEWER IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

Interviewer’s Name Interviewer’s Signature Date

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

Volunteer’s Name Volunteer’s Signature Date

Informed Consent Form: Key Informant Discussion—Referral Agent

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of referral agents. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries.

You are being asked to participate in a discussion because you are a referral agent who works with Medicare beneficiaries to receive durable medical equipment.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the discussions and other forms of data collection, analysis, and reporting. Andrea Hassol is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part in this discussion if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

The discussion notes will be labeled with a study code, not your name. Notes and reports from the discussion will be stored in a secure location (i.e. locked office file cabinet) and electronic materials will be stored in a password-protected computer. Your comments will be presented in reports to the government in summary form. Your name will not be included in any reports.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the discussion.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the discussion, you will not be penalized and your relationship with the Centers for Medicare & Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Andrea Hassol of Abt Associates (617 349-2488) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Hassol at:

Andrea Hassol
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STATEMENT BY INTERVIEWER IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

Interviewer’s Name

Interviewer’s Signature

Date

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

Volunteer’s Name

Volunteer’s Signature

Date

Informed Consent Form: Key Informant Discussion—Supplier

Abt Associates Inc. has been hired by the Centers for Medicare & Medicaid Services (CMS) to conduct an evaluation of the durable medical equipment, prosthetics, orthotics & suppliers (DMEPOS) competitive bidding program. As part of that evaluation Abt Associates is conducting discussions to learn about the perceptions and experiences of suppliers of durable medical equipment. These discussions will help CMS understand the affect of the program on referral agents, suppliers and Medicare beneficiaries. You are being asked to participate in a discussion because you are a DMEPOS supplier who provides durable medical equipment to Medicare beneficiaries.

A total of 12 discussions with different groups are being held as part of the study. Abt Associates will conduct the discussions and other forms of data collection, analysis, and reporting. Andrea Hassol is the Principal Investigator at Abt Associates.

PROCEDURES

You will be asked to discuss the Medicare competitive bidding program in this discussion that will last approximately 45 minutes.

The discussion will be confidential. You can refuse to take part in this discussion if you wish without losing any rights or benefits related to your professional relationship with CMS. You can also refuse to answer any particular question during the discussion, without affecting your continued participation in the discussion or your relationship with CMS.

RISKS OF TAKING PART IN THE STUDY

The researcher does not foresee any possible risks to you from participating in this discussion, other than the minimal risk that your confidentiality might not be preserved.

COSTS AND FINANCIAL RISKS

There will be no costs charged to you for participating in the discussion.

POSSIBLE BENEFITS OF TAKING PART IN THE STUDY

There may not be any direct benefit to you from being interviewed, although you may benefit from the opportunity to share your experiences.

COMPENSATION

You will not receive compensation.

VOLUNTARY PARTICIPATION AND WITHDRAWAL STATEMENT

It is up to you to decide whether to be interviewed. If you decide not to participate in the discussion, you will not be penalized and your relationship with the Centers for Medicare &

Medicaid Services will not be affected. Even if you agree to participate, you are not required to answer all the questions you are asked.

QUESTIONS

You understand that you may phone Andrea Hassol of Abt Associates (617 349-2488) to have my questions answered. You can also phone Ann Meadow at CMS (410 786-6022). You can mail a letter to Ms. Hassol at:

Andrea Hassol
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

You may also phone Teresa Doksum, the chairperson of Abt Associates’ Institutional Review Board (617 349-2896) if you have other questions about your rights as a focus group participant. All of these numbers are toll calls.

STATEMENT BY INTERVIEWER IN THIS RESEARCH STUDY

I have explained the purpose of this research, the study procedures, identifying the potential risks and benefits. I have answered any questions regarding the research study to the best of my ability.

Interviewer’s Name Interviewer’s Signature Date

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS DISCUSSION

I have read and understand this information. I have had all my questions answered fully and I freely and voluntarily choose to participate in the focus group. I have been given a copy of this consent form.

Volunteer’s Name Volunteer’s Signature Date

INFORMED CONSENT SCRIPT: Comparison Area Key Informant Discussion: Beneficiary Group/Advocate

Hello/Good morning/Good afternoon...May I speak with...(if not available, leave a message)

My name is [Interviewer name]. I am calling from Abt Associates Inc. You are scheduled to conduct an interview on the evaluation of the Centers for Medicare and Medicaid Services' Durable Medical Equipment, Prosthetic, Orthotic Supplies' competitive bidding program. Is this still a good time to do the interview?

[If no] May I reschedule the interview at a time that is convenient for you?

[If yes] Before we begin, I need to review a few details about the study with you.

As you may or may not know, Medicare is implementing a new fee schedule for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) in various areas of the United States. The purpose of our study is to evaluate the affect of the competitive bidding program on suppliers, beneficiaries and referral agents. The study is being conducted by Abt Associates on behalf of the Centers for Medicare and Medicaid Services (CMS).

You were chosen to participate as a member of a beneficiary group or an advocate to provide an understanding of the current environment for Medicare beneficiaries and their durable medical equipment in your area, as a comparison. [If relevant] You were also recommended by [name referral].

Our interview today should last about 45 minutes. Please understand that your participation in this study is voluntary and that if you choose not to participate you will not be penalized in any way. You can refuse to answer any question I ask and may even ask to stop the interview at any time. This interview will not be tape-recorded. Instead I will take notes. These notes will be used to create summaries, which will not include your personal information, and will be used to write a report to CMS on the education and outreach program for the new Medicare drug benefit. Do you have any questions?

If you have any questions that I may not be able to answer at this time, or at any time after this interview, you may contact _____, at the Centers for Medicare and Medicare Services (____) ____-____and she will be happy to assist you. Note, this is a toll call.

Given the information that I have just reviewed with you, do you still wish to participate in this study/interview?

If Yes, _____ [Interviewer's Initials}. Great. Let me begin with the first question.

If No, _____ [Interviewer's Initials}. Great. That is fine. We appreciate your time. Thank you.

INFORMED CONSENT SCRIPT: Comparison Areas Key Informant Discussion—Referral Agent

Hello/Good morning/Good afternoon...May I speak with...(if not available, leave a message)

My name is [Interviewer name]. I am calling from Abt Associates Inc. You are scheduled to conduct an interview on the evaluation of the Centers for Medicare and Medicaid Services' Durable Medical Equipment, Prosthetic, Orthotic Supplies' competitive bidding program. Is this still a good time to do the interview?

[If no] May I reschedule the interview at a time that is convenient for you?

[If yes] Before we begin, I need to review a few details about the study with you.

As you may or may not know, Medicare is implementing a new fee schedule for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) in various areas of the United States. The purpose of our study is to evaluate the affect of the competitive bidding program on suppliers, beneficiaries and referral agents. The study is being conducted by Abt Associates on behalf of the Centers for Medicare and Medicaid Services (CMS).

You were chosen to participate as a referral agent to provide an understanding of the current environment for Medicare beneficiaries and their durable medical equipment in your area, as a comparison. [If relevant] You were also recommended by [name referral].

Our interview today should last about 45 minutes. Please understand that your participation in this study is voluntary and that if you choose not to participate you will not be penalized in any way. You can refuse to answer any question I ask and may even ask to stop the interview at any time. This interview will not be tape-recorded. Instead I will take notes. These notes will be used to create summaries, which will not include your personal information, and will be used to write a report to CMS on the education and outreach program for the new Medicare drug benefit. Do you have any questions?

If you have any questions that I may not be able to answer at this time, or at any time after this interview, you may contact Ann Meadows, at the Centers for Medicare and Medicare Services (____) ____-____ and she will be happy to assist you. Note, this is a toll call.

Given the information that I have just reviewed with you, do you still wish to participate in this study/interview?

If Yes, _____ [Interviewer's Initials]. Great. Let me begin with the first question.

If No, _____ [Interviewer's Initials]. That is fine. We appreciate your time. Thank you.

Informed Consent Script: Comparison Areas Key Informant Discussion—Supplier

Hello/Good morning/Good afternoon...May I speak with...(if not available, leave a message)

My name is [Interviewer name]. I am calling from Abt Associates Inc. You are scheduled to conduct an interview on the evaluation of the Centers for Medicare and Medicaid Services' Durable Medical Equipment, Prosthetic, Orthotic Supplies' competitive bidding program. Is this still a good time to do the interview?

[If no] May I reschedule the interview at a time that is convenient for you?

[If yes] Before we begin, I need to review a few details about the study with you.

As you may or may not know, Medicare is implementing a new fee schedule for durable medical equipment, prosthetic, and orthotic supplies (DMEPOS) in various areas of the United States. The purpose of our study is to evaluate the affect of the competitive bidding program on suppliers, beneficiaries and referral agents. The study is being conducted by Abt Associates on behalf of the Centers for Medicare and Medicaid Services (CMS).

You were chosen to participate as supplier to provide an understanding of the current environment for Medicare beneficiaries and their durable medical equipment in your area, as a comparison. [If relevant] You were also recommended by [name referral].

Our interview today should last about 45 minutes. Please understand that your participation in this study is voluntary and that if you choose not to participate you will not be penalized in any way. You can refuse to answer any question I ask and may even ask to stop the interview at any time. This interview will not be tape-recorded. Instead I will take notes. These notes will be used to create summaries, which will not include your personal information, and will be used to write a report to CMS on the education and outreach program for the new Medicare drug benefit. Do you have any questions?

If you have any questions that I may not be able to answer at this time, or at any time after this interview, you may contact Ann Meadows, at the Centers for Medicare and Medicare Services (____) ____-____ and she will be happy to assist you. Note, this is a toll call.

Given the information that I have just reviewed with you, do you still wish to participate in this study/interview?

If Yes, _____ [Interviewer's Initials]. Great. Let me begin with the first question.

If No, _____ [Interviewer's Initials]. That is fine. We appreciate your time. Thank you.